

Foliodrape® Protect, Extremity Set (Art. No. 938 915)



Spec.-no.:	D6.1010m
Department:	CMO-DOE
Date:	2013-01-21

1. General Product Description

Foliodrape® Protect Extremity Set is for interventions in the area of the leg (arthroscopy, knee, extremities).

The *Foliodrape® Protect* Extremity Set carries the CE-mark according to EU directive 93/42/EWG for medical devices and is classified as class I medical device.

A conformity assessment has been performed for *Foliodrape® Protect* and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of *Foliodrape® Protect* Extremity Set, therefore, is ensured if the product is used in line with the intended purpose.

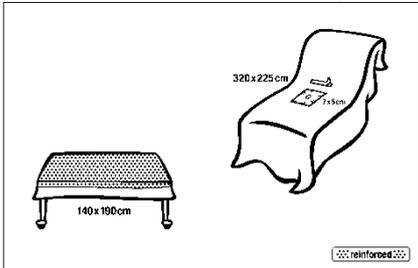
2. Application / Indication

Foliodrape® Extremity Set is a disposable product for sterile draping of the patient and the theatre equipment.

3. Presentations:

Art. Nr. 938 915	Foliodrape® Protect Extremity Set
	sterile, 9 Sets per dispenser, 1 dispenser per transport carton
	Abmessungen Dispenser: 545 x 374 x 234 mm (L x B x H)
	Abmessungen Transportkarton: 590 x 390 x 250 mm (L x B x H)

4. Product characteristics

<p>Content:</p> 	1 table cover reinforced 140 x 190 cm
	1 extremity drape sheet 225 x 320 cm (fenestration 5 x 7 cm) with elastic collar and hook-loop Fastener
	1 crepe paper 100 x 100 cm
Sterilization:	With ethylene oxide gas

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5. Product requirements:

Foliodrape® Protect corresponds to all requirements of European standard for surgical drapes EN 13795, for the highest performance level "High performance, critical area".

For Details see Technical Data sheet of the base material (D 6.1005), and table cover (D 6.1005d).

6. Labelling Lot no. with 9-digit code:

e.g.: **5023XXX**

LOT	5	023	XXXXX
	year of production	Serial production order	For internal purposes only

Expiry date:

e.g.  2011 – 01
year month

Shelf life: 5 years

The product will be sterile during this period as long as the packaging is not damaged and the storage conditions are kept.

7. Packaging

Foliodrape® Protect Extremity set wrapped into sterile crepe paper, sealed into sterile packaging (peeling pouch) according to EN ISO 11607 and EN 868. The peel pouch is packed into folding box and transport carton, sealed with adhesive tapes and stored on euro-pallet.

Date: 2013-01-21

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i. A.



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